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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,271	09/03/2002	Thomas Niehr	F-7322	5161
28107	7590	06/15/2004	EXAMINER	
JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168			CHORBAJI, MONZER R	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,271

Applicant(s)

NIEHR ET AL.

Examiner

MONZER R CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This non-final office action is in response to the amendment received on 03/19/2004

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 4 and 24 teaches heating the air to an activation temperature first then heating the peroxide aerosol to the sterilizing starting temperature. Such a limitation is not explained in the specification. Claims 4 and 24 were examined as explained above.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 12-31 have been renumbered as 11-29. Thus, the total number of claims is 1-29.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered

indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "temperature-sensitive plastic", and the claim also recites "especially PET bottles" which is the narrower statement of the range/limitation. Applicant should include the narrower limitation in one of the dependent claims.

5. Claims 2 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, applicant recites the limitation "peroxide is fogged into an aerosol". On page 19 of the tenth edition of the Merriam-Webster's Collegiate Dictionary, fog, smoke, and mist are all examples of aerosol. Does the applicant claim means to create peroxide aerosol? Clarification is needed since the specification does not explain this limitation. The same applies to claim 21. Both

claims are interpreted as having means to produce a peroxide aerosol.

Clarification is needed to understand the meaning of claims 2 and 21.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claims 1-2, 4-8, 10-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vokins et al (U.S.P.N. 5,178,841) in view of Palaniappan et al (U.S.P.N. 6,120,730).

With respect to claim 1, Vokins et al teaches a method for sterilizing containers (col.4). The containers are advanced the containers periodically (periodically is equivalent to the predetermined time interval between indexing movements along the conveyor system in col.3, lines 22-25). The hydrogen peroxide aerosol (fine spray droplets of hydrogen peroxide is equivalent to the definition of an aerosol in col.2, lines 50-53) is heated to a starting temperature by heated sterile air (col.4, lines 37-40) such that a condensation film is formed on the inner surfaces of the containers (in col.4, lines 28-30 teaches the presence of hydrogen peroxide droplets on the inner surfaces of the containers. Those droplets are equivalent to the layer of condensation). Then sterile air heated to a higher temperature than the starting temperature of the peroxide aerosol is blown into the containers to evaporate the condensate (col.4, lines 44). However, Vokins et al fails to disclose two limitations. The first is to explicitly disclose sterilizing a temperature-sensitive plastic containers and the second is to further apply sterile air to the containers. Palaniappan et al teaches sterilizing plastic bottles using hydrogen peroxide gas (abstract, lines 1-12). In addition, Palaniappan et al teaches the concept of repeating blowing heated sterile air into plastic bottles (34, 36, and col.5, lines 52-54). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Vokins et al to

include plastic bottles in order to sterilize various types of containers
(Palaniappan et al, abstract, lines 11-13).

With respect to claims 2 and 4, the aerosol (aerosol is equivalent to fog) is produced by means (1) at ambient temperature since Vokins et al heats the peroxide aerosol to a first temperature (5 and the unlabeled arrows in figure 1) after it is produced. The incoming air is heated first then mixed with the aerosol as in figure 1, such that the temperature of the sterile air after being heated but before is mixed with the aerosol is higher (an activation temperature) than its temperature after mixing with the peroxide aerosol (sterilization starting temperature).

With respect to claims 5-8,10-12, and 14, Palaniappan et al method teaches applying the hydrogen gas and the air separately (28 and 34) such that hydrogen gas is introduced into plastic bottles in two separate and consecutive steps (63 and 64) with pausing time intervals in between such steps (col.4, lines 38-45). In addition, sterile air is blown inside plastic bottles in two separate steps (two separate nozzles113). Further, the concept of multiple and separate application of sterile air is taught in the Palaniappan et al reference (34, 36, and col.5, lines 52-54). Palaniappan et al discloses a velocity value for the blown sterile air (col.9, bottom of table one) such that velocity and flow rate are intrinsically related to each other. Adjusting the velocity of the sterile air intrinsically results in changing the value of the flow rate such that the desired velocity of the sterile air depends on the type of the containers to be sterilized. For example, big containers require more air for drying purposes versus small

containers. The Palaniappan et al reference discloses a volume flow rate for hydrogen peroxide (col.5, lines 37-38) such that volume and flow rate are intrinsically related to each other. Adjusting the flow rate of the peroxide intrinsically results in changing the value of the volume such that the desired volume for the peroxide depends on the degree of sterilization intended and on the size of containers to be treated.

10. Claims 9, 15-20, and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vokins et al (U.S.P.N. 5,178,841) in view of Palaniappan et al (U.S.P.N. 6,120,730) and further in view of Reinecke (DE 3339930).

With respect to claim 15, the teachings of both Vokins et al and Palaniappan et al have been previously presented with respect to independent claim 1. In addition, with respect to claim 15, Vokins et al method mixes the peroxide aerosol with the heated air then applies the mixture inside containers (col.4, lines 1-18). The use of the heated air is to vaporize or dissipates (scatter) the aerosol before it is applied to the inner surfaces of containers. However, both Vokins et al and Palaniappan et al fail to disclose an activation temperature of about 90 to 120 degree Celsius. Reinecke teaches heating sterile air to a temperature range of between 120 to 140 degree Celsius (abstract, lines 9-10). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Vokins et al to include heating the sterile air to about 120 degree Celsius in order to insure that all of the hydrogen peroxide has been removed from the inner surfaces of the plastic bottles.

With respect to claims 9, 24, and 28, Reinecke teaches heating sterile air to a temperature of 110 degree Celsius (abstract, lines 4-5).

The limitations for claims 16-19, 25-27, and 29 have previously been addressed above with respect to claims 5-8, 10-12, and 14.

The limitations for claims 20 and 23 have previously been addressed above with respect to claims 2 and 4.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vokins et al (U.S.P.N. 5,178,841) in view of Palaniappan et al (U.S.P.N. 6,120,730) and further in view of Dronet (FR 2666299).

With respect to claim 3, both Vokins et al and Palaniappan et al fails to disclose heating the aerosol to a temperature of about 60 to 90 degree Celsius. However, Dronet teaches heating the aerosol to a temperature of about 80 degree Celsius (use/advantages, lines 3-4). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Vokins et al by heating the sterile air to a temperature of about 80 degree Celsius since such a temperature is the optimum temperature for hydrogen peroxide sterilization (Dronet, use/advantage, lines 3-4).

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vokins et al (U.S.P.N. 5,178,841) in view of Palaniappan et al (U.S.P.N. 6,120,730) and further in view of Hatanaka et al (U.S.P.N. 4,797,255).

With respect to claim 13, both Vokins et al and Palaniappan et al fail to disclose a time range for blowing sterile air. Hatanaka et al teaches a time range of 5 seconds and less of blowing sterile air for removal of deposited hydrogen

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peroxide (col.8, lines 5-7). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Vokins et al by blowing sterile air for 5 seconds or less for the complete removal of the hydrogen peroxide condensate (Hatanaka et al, col.8, lines 3-7).

13. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vokins et al (U.S.P.N. 5,178,841) in view of Palaniappan et al (U.S.P.N. 6,120,730) and further in view of Reinecke (DE 3339930) and Dronet (FR 2666299).

With respect to claims 21-22, Vokins et al, Palaniappan et al, and Reinecke all fail to disclose heating the aerosol to a temperature of about 60 to 90 degree Celsius. However, Dronet teaches heating the aerosol to a temperature of about 80 degree Celsius (use/advantages, lines 3-4). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of Vokins et al by heating the sterile air to a temperature of about 80 degree Celsius since such a temperature is the optimum temperature for hydrogen peroxide sterilization (Dronet, use/advantage, lines 3-4).

Response to Arguments

14. Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone

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number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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06/09/2004

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